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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/536,735	03/28/2000	Simone Gauch	QGN-009.2US	5502

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EXAMINER
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SISSON, BRADLEY L

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/536,735	<b>Applicant(s)</b> GAUCH ET AL.	
	<b>Examiner</b> Bradley L. Sisson	<b>Art Unit</b> 1634	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 April 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) 9-13,20,37-56,58-75,113-116 and 121-129 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) 9-13,20,37-56,58-75,113-116 and 121-129 is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment( )**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other:  |

## **DETAILED ACTION**

### ***Specification***

1. The amendment filed 28 April 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material, which is not supported by the original disclosure, is as follows: the recitation of "hydroxy compound" in claims 9 and 58; and "hydroxyl derivatives" in claim 54.
2. Applicant is required to cancel the new matter in the reply to this Office Action.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 9-13,20,37-56,58-75,113-116 and 121-129 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As a result of the amendment of 28 April 2003, claim 9 was amended. It is noted with particularity that the language of b(i) was amended and b(ii) was introduced. Page 11, of the amendment directs attention to page 18, lines 6-13, of the

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specification as providing support for the newly added language. For convenience, the specified lines are reproduced below:

To carry out the process according to the invention, first all hydroxyl derivatives of aliphatic or acyclical saturated or unsaturated hydrocarbons are eligible as alcohols. It is irrelevant whether these compounds contain one, two, three, or more hydroxyl groups-such as polyvalent C<sub>1</sub>-C<sub>5</sub> alkanoids, e.g., ethylene glycol, propylene glycol or glycerin.

In addition, the alcohols that can be used according to the invention also include sugar derivatives, the so-called alditols, as well as phenols, e.g., polyphenols.

Among the aforementioned hydroxy compounds, C<sub>1</sub>-C<sub>5</sub>-alkanols, such as methanol, ethanol, n-propanol, tert-butanol and pentanols, or mixtures of such alcohols, are most preferred. (Emphasis added)

The recitation of "a hydroxy compound" in Claim 9, b(ii) is considered to be broader than the specific embodiments recited above. Accordingly, the specification does not support the breadth of scope now asserted in the amended claims. Additionally, the specification does not reasonably suggest that applicant had contemplated such breadth of scope at the time of filing. While applicant may consider the broader application of "hydroxy compounds" to be obvious to the skilled artisan, obviousness cannot be relied upon in satisfying the written description requirement. In support of this position, attention is directed to the decision in *University of California v. Eli Lilly and Co.* (Fed. Cir. 1997) 43 USPQ2d at 1405, citing *Lockwood v. American Airlines Inc.* (Fed. Cir. 1997) 41 USPQ2d at 1966:

Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.

5. For the above reasons, and in the absence of convincing evidence to the contrary, claims 9-13,20,37-56,58-75,113-116 and 121-129 are rejected as not being adequately supported by the original disclosure.

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6. Claims 9-13,20,37-56,58-75,113-116 and 121-129 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

7. As presented above, the presently claimed invention encompasses embodiments not originally disclosed by the original disclosure. It is well established that one cannot enable the use of a product, or practice of a method when they do not yet possess same. Accordingly, claims 9-13,20,37-56,58-75,113-116 and 121-129 are not enabled by the original disclosure.

***Claim Rejections - 35 USC § 102/103***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 9-13, 20, 37-56, 58-75, 113-116, and 121-129 remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lee et al. (US Patent 4,798,789).

13. Lee et al., column 7, disclose a method of isolating mRNA from a sample whereby a chaotropic agent is used. The mRNA is bound to oligo-dT cellulose. The presence of cellulose is considered to meet the requirements that a hydroxyl compound is present as well as the requirement that the nucleic acid sample be applied to a "non-siliceous surface."

14. Lee et al., columns 13-14, disclose the isolation of DNA from cells and the reversible immobilization of the nucleic acid to a cellulose column. Column 14 teaches that the immobilization and washes were performed with a buffer that was at 0° C. Elution was effected by the introduction of "water at room temperature." The aspect of having the DNA reversibly immobilized on a cellulose column meets the requirement that the sample be brought into contact

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with a non-siliceous surface, and that the sample be in contact with a hydroxy compound (the cellulose resin). The presence of sodium chloride meets the requirement that a salt of a metal be present.

15. Column 14 discloses performing additional steps on the released DNA, e.g., precipitation and digestion as well as additional extraction steps where phenol was used. Such disclosures meet a limitation of claim 20.

16. The presence of NaCl in the buffer meets a limitation of claims 46-48 in that a sodium halide is present.

17. For the above reasons, and in the absence of convincing evidence to the contrary, the invention of claims 9-13,20,37-56,58-75,113-116 and 121-129 remain rejected under 35 USC 103 as being obvious in view of the prior art of record.

Response to argument

18. Argument is advanced at page 17 of the response that the claimed method, unlike the prior art, does not rely upon a covalent modification to alter the sequence of the nucleic acid and does not depend on the presence of a complementary second nucleic acid that serves as an essential reagent for carrying out the isolation process. Said argument has been fully considered and has not been found persuasive towards the withdrawal of the rejection. It is noted with particularity that the claimed method encompasses just such an embodiment, whether applicant had intended such breadth of scope is not persuasive. In short, the name of the game is the claims and applicant is arguing limitations not found therein.

19. Argument is also advanced on page 17 of the response that the prior art does not disclose using two particular component compounds as required in Claim 9, e.g., a salt of a metal and a

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hydroxy compound. As shown above, the prior art teaches explicitly of including sodium chloride in the solution and that the nucleic acid is reversibly immobilized to cellulose resin. Cellulose, which is comprised of saccharide units, meets the limitation of a hydroxy compound. In support of this position, attention is directed to page 18, line 10, which states explicitly that sugar derivatives are considered to be an embodiment of a hydroxyl compound.

Argument is advanced at page 18 of the response that “a fair reading of the protocol in Lee (see, above) would indicate to persons of ordinary skill in this art that the elution of dT-tailed DNA that is bound to oligo(dA) cellulose was indeed carried out at room temperature, e.g., around 25°C, at which hydrogen bonding of complementary base paired nucleotides (dA:dT), would be *more destabilized* that at lower temperature, as in Applicant’s process.” The above argument has been fully considered and has not been found persuasive. It is noted that the column had been effectively chilled to 0°C by repeated passages of buffers chilled to 0°C. While a elution buffer at room temperature was added to the column, such is not considered to alter the aspect of the DNA becoming dissociated from the resin upon the first wave of the elution buffer passing over the column, whereby the elution buffer would be cooled by the column. While the column and the elution buffer would reach a thermoequilibrium at some point with sufficient passage of sufficient quantities of elution buffer, the prior art is considered to meet the requirement that actual elution, not the temperature of the buffer prior to it coming into contact with the column, would occur within a temperature range of from 10°C to 0°C.

20. It is noted that applicant has provided evidence to support the position that warmer elution buffer result in less stable nucleic acid binding as compared to the claimed method. Such



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improvement, or unexpected property needs to flow from the originally-filed application, not from post-filing technical disclosures.

21. Assuming *arguendo*, that the elution buffer was not within the prescribed range, a position that the Office does not concede, such would still not overcome the obviousness of the rejection as optimization of buffer temperature is considered to be a matter of routine optimization and not a point of novelty. It is well settled that routine optimization is not patentable, even if it results in significant improvements over the prior art. In support of this position, attention is directed to the decision in *In re Aller, Lacey, and Hall*, 105 USPQ 233 (CCPA 1955):

Normally, it is to be expected that a change in temperature, or in concentration, or in both, would be an unpatentable modification. Under some circumstances, however, changes such as these may impart patentability to a process if the particular ranges claimed produce a new and unexpected result which is different in kind and not merely in degree from the results of the prior art. In *re Dreyfus*, 22 C.C.P.A. (Patents) 830, 73 F.2d 931, 24 USPQ 52 ; In *re Waite et al.*, 35 C.C.P.A. (Patents) 1117, 168 F.2d 104, 77 USPQ 586 . Such ranges are termed "critical" ranges, and the applicant has the burden of proving such criticality. In *re Swenson et al.*, 30 C.C.P.A. (Patents) 809, 132 F.2d 1020, 56 USPQ 372 ; In *re Scherl*, 33 C.C.P.A. (Patents) 1193, 156 F.2d 72, 70 USPQ 204 . However, even though applicant's modification results in great improvement and utility over the prior art, it may still not be patentable if the modification was within the capabilities of one skilled in the art. In *re Sola*, 22 C.C.P.A. (Patents) 1313, 77 F.2d 627, 25 USPQ 433 ; In *re Normann et al.*, 32 C.C.P.A. (Patents) 1248, 150 F.2d 708, 66 USPQ 308 ; In *re Irmischer*, 32 C.C.P.A. (Patents) 1259, 150 F.2d 705, 66 USPQ 314 . More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. In *re Swain et al.*, 33 C.C.P.A. (Patents) 1250, 156 F.2d 239, 70 USPQ 412 ; *Minnesota Mining and Mfg. Co. v. Coe*, 69 App. D.C. 217, 99 F.2d 986, 38 USPQ 213 ; *Allen et al. v. Coe*, 77 App. D. C. 324, 135 F.2d 11, 57 USPQ 136. (Emphasis added)

22. Accordingly, and in the absence of convincing evidence to the contrary, the rejection is maintained.

***Conclusion***

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

24. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is 703-308-3978. The examiner can normally be reached on Monday through Thursday from 6:30 AM to 5 PM.

26. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

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27. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.



Bradley L. Sisson  
Primary Examiner  
Art Unit 1634

BLS  
August 10, 2003